

**§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.**

(a) *Accreditation organization inspection results.* HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results.* Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *HCFA validation inspection results.* HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

**§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.**

(a) *Comparability review.* In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(1) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by § 493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures.* (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a

State licensure program must reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that HCFA may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.